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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/138,735	08/24/1998	GLAUCIA PARANHOS-BACCALA	WPB-36400B	4465

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

27

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/138,735

Applicant(s)

Baccala et al

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 5, 7, 8, 10-27, 32, 34, and 36-42 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 2 is/are allowed.
- 6) ☒ Claim(s) 5, 7, 8, 10-27, 32, 34, and 36-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Applicant's amendment filed December 9, 2002 (Paper Number 26) has been received and entered. New claims 41-42 have been added, consequently claims 1, 2, 5, 7, 8, 10-27, 32, 34, and 36-42 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 5, 7, 8, 10-27, 32, 34, and 36-40 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained. Additionally this rejection is applied to newly added claims 41-42.

Applicant's are asserting that the claims have been amended to recite "consisting essentially of." Applicant's point to MPEP 2111.03, wherein the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristics of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461,463 (CCPA 1976).

Applicant's arguments have been fully considered but are not found to be fully persuasive.

Applicant's arguments are not found to be persuasive in view of MPEP 2111.03 which recites that "absent a clear indication in the specification or claims of what the basic and novel

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characteristics actually are “consisting essentially of” will be construed as equivalent to “comprising.” See e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355. Furthermore, as stated in MPEP 2111.03 the phrase “consisting essentially of” is typically used and defined in the context of compositions of matter, although their use as a modifier of method steps is also deemed appropriate. However, it is unclear how consisting essentially of is applied to solely a nucleic acid sequence. The phrase is deemed to still be equivalent to comprising in view of MPEP 211.03, given that the specification does not define the basic and novel characteristics of the claimed material in light of the phrase “consisting essentially of.”

For reasons of record in Paper Number 25, as well as the reasons set forth above, this rejection is maintained.

2. The rejection of claims 5, 7, 8, 10-27, 32, 34, and 36-40 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained. Additionally, this rejection is applied to newly added claims 41-42.

Applicant's assertions are essentially identical to the arguments set forth above in paragraph 1, and have been addressed accordingly in paragraph 1.

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Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record in Paper Number 25, as well as the reasons set forth above, this rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The rejection of claims 5, 8, 10-11, 17, 25-26, 32, 34, 39 and 40 under 35 U.S.C. 102(b) as being anticipated by Birkett *et al* is maintained.

Applicant's are asserting that it is well known to those skilled in the art that 100% homology is not necessary for a primer to bind to a target sequence. Applicant's assert that

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random hexamer kits do not include every possible combination of six nucleotides, as every conceivable sequence is not necessary for successful priming. Applicant's further assert that in order for a prior art reference to anticipate a claimed invention on the ground that a limitation is inherently disclosed in the reference, the inherency must be certain. The fact that a prior art reference may have the characteristics of the claimed product is not sufficient. *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

Applicant's arguments have been fully considered but are not found to be fully persuasive.

First, Applicant's assert that it is well known that 100% homology is not necessary for a primer to bind to a target sequence. This point is readily agreed upon.

Second, Applicant's assert that random hexamer kits do not include every possible combination of six nucleotides, as every conceivable sequence is not necessary for successful priming. While it is agreed that every conceivable sequence of six consecutive nucleotides is not contained within the kit disclosed by Birkett et al, the claims do not require a 100% match in the first place, rather only 85% identity is required. Furthermore, as argued by Applicant's 100% homology is not necessary for a primer to bind to a target sequence. This combined with the fact that the claims only require 85% homology, translates into primers having mismatches within a hexamer nucleic acid sequence still being deemed anticipatory. Furthermore, the sequence can bind anywhere within SEQ ID NO: 1, a nucleic acid sequence of 3,402 bases. The ability of the

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randomly generated six consecutive primers disclosed by Birkett, when permitted to contain less than 100% homology will inherently bind to SEQ ID NO: 1 under the recited conditions.

Since the Patent office does not have the facilities for examining and comparing applicants' product with the product of the prior art reference, the burden is on applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

The claims are drawn to isolated probe which is identical or fully complementary to nucleotides 1232-2207 of SEQ ID NO: 1, wherein said probe contains at least 5 and no more than 100 nucleotides.

Birkett *et al* (U.S. Patent Number 5,302,527) disclose of random priming with a mixed hexamer oligonucleotide kit (Multiprime Kit, Amersham). (See column 15 lines 25-30).

In view that the isolated hexamer oligonucleotide primers contain every possible nucleotide sequence of six consecutive nucleotides, and that these sequences will inherently match those of SEQ ID NO: 1, the disclosure of the hexamer kit by Birkett *et al* is seen to anticipate the claimed invention.

The following new grounds of rejection are applied to the amended claims:

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Claim Rejections - 35 USC § 112

4. Claims 41-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant's have filed new claims 41-42 which recite a probe having "7-100" or "7-30" nucleotides. However, Applicant has not pointed out support for the newly filed limitations of a probe having a minimum of seven nucleotides. Applicant is required to demonstrate clear support within the specification (page and line number) or cancel the newly added material.

Claims 1-2 are allowed.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

February 21, 2003